

REMARKS

The Claims have not been amended in this response and therefore remain the same as filed.
Claims 1-34 are currently pending in this application.

Information Disclosure Statement

An IDS is submitted herewith containing the two references (US Patent Nos. 5,718,239 and 5,893,845) listed in the present specification for consideration by the Examiner.

It should be noted that US Patent No. 5,893,845 is a part of the cited EP 1,208,862 patent family. Furthermore there is a typographical error in the EP 1,208,862 patent as the correct spelling of the first listed inventor is Newby, and not “Mewby”.

Claims Rejections – 35 USC § 102

(A) Claims 1-9, 13-16, 19, 20, 22, 23, 25-32, and 34 are rejected under 35 U.S.C. 102(a) as being anticipated by E.P. Patent No. 1,208,862 to Newby et al. (“Newby”).

This rejection is respectfully traversed.

Of the claims rejected, claims 1, 19, 22, 27, are independent, with the remaining claims dependent thereon.

Claim 1 recites, among other things:

*a lock for releasably maintaining the shield in the fully retracted position;
an actuator for releasing the lock; and
a retaining member engageable with the shield,
wherein activation of the actuator causes the lock to be released with the retaining member preventing the shield from moving toward the fully extended position when engaged therewith, and wherein the shield is prevented from moving to the fully extended position until the retaining member is disengaged from the shield.*

Claim 19 recites, among other things:

*a retaining member moveably mounted on the hub and engageable with the telescoping shield when a blood collection container is received in the needle holder,
wherein the retaining member holds the telescoping shield from moving toward the fully extended position when engaged therewith, and wherein removal of the blood collection*

container from the needle holder causes the retaining member to disengage from the telescoping shield, thereby releasing the telescoping shield such that the telescoping shield will move toward the fully extended position.

Claim 22 recites, among other things:

a retaining member moveably mounted on the hub and engageable with the telescoping shield when a blood collection tube is positioned within the needle holder, wherein insertion of a blood collection tube in the needle holder activates the actuator to cause the lock to be released from the retaining member holding the shield against the spring bias, and wherein removal of the blood collection tube from the needle holder disengages the retaining member from the telescoping shield, releasing the spring bias and allowing the telescoping shield to be moved in a direction toward the fully extended position.

Applicant submits that Newby fails to disclose at least the claimed features of: a retaining member which prevents deployment of the safety shield to the fully extended shielded position upon actuation of the safety shield.

Newby discloses a safety needle assembly, incorporating a telescoping shield that extends over the distal end of the needle cannula when released by an actuator. In particular, when the actuator is triggered the telescoping shield extends to contact the skin of a patient (See Fig. 4) and /or to the fully extended and locked position over the distal end of the needle cannula (See Figs 5 and 9).

In contrast, the shield of the present application does not advance to the fully extended position upon activation as it is held by the retaining member, such that the retaining member has to be released in order for the shield to advance to the fully extended position.

The Examiner is of the opinion that Newby discloses a shieldable needle assembly comprising a retaining member (57) engageable with the shield. Applicant respectfully submits that retention rib (57) of Newby is part of the locking mechanism which retains the telescoping shield (3) in the retracted position (See paragraph [0023], Figs 3 and 7 shown below, emphasis added).

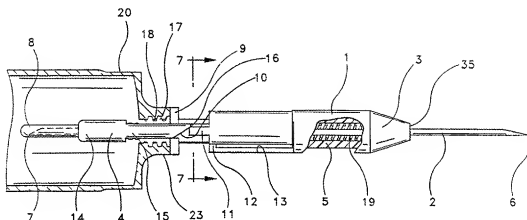


FIG. 3 Newby

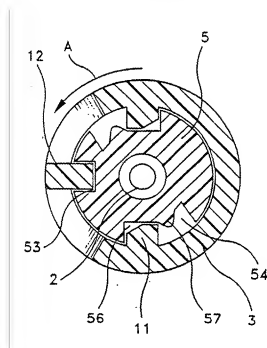


FIG. 7 Newby

[0023] Fig. 7 is a cross-sectional view of needle assembly 1 shown in Fig. 3 at its starting retracted position along lines 7-7. As shown in Fig. 7, tab 12 of torsion spring 13 is located in torsion spring track 53 in needle hub 5 and each shield lug 11 is located in a respective proximal pocket 56. Each of these lugs 11 are held in each pocket 56 by a respective retention rib 57. When closure 31 is penetrated by distal end 7 of cannula 2 and sleeve 14 on actuator 4 causes distal lateral movement of actuator 4 and mating of surfaces 10 and 16, shield 3 is rotated in the direction of arrow A and lugs 11 move over retention ribs 57 into their respective channels 54. Once lugs 11 are in their respective channel 54,

compression spring 19 causes distal movement of shield 3 until it reaches the partially extended position shown in Fig. 4.

Therefore the retention rib (57) of Newby does not prevent the advancement of the shield after activation of the actuator (4).

Claim 27 recites, among other things:

inserting a blood collection tube into the needle holder, thereby engaging the retaining member with the telescoping shield and causing the retaining member to prevent the telescoping shield from being biased to a shielded position encompassing the needle cannula; and removing the blood collection tube from the needle holder, thereby disengaging the retaining member from the telescoping shield and causing the telescoping shield to be biased toward the shielded position encompassing the needle cannula.

Applicant submits that Newby fails to disclose at least the claimed features of: the insertion of a blood collection tube into the needle holder, thereby engaging the retaining member with the telescoping shield and causing the retaining member to prevent the telescoping shield from being biased to a shielded position encompassing the needle cannula; and the removal of the blood collection tube from the needle holder, thereby disengaging the retaining member from the telescoping shield and causing the telescoping shield to be biased toward the shielded position encompassing the needle cannula.

As discussed previously in the rejection of claims 1, 19 and 27, Newby fails to disclose a retaining member as claimed. Furthermore after activation, the safety shield of Newby is only prevented from advancing to the fully extended and locked position by the presence of the patients' skin (see paragraph [0020] lines 38 to 44 as shown below) and not by a retaining member:

After actuator 4 has triggered and transported telescoping shield 3 from the retracted position shown in Fig. 3 to the partially extended position shown in Fig. 4, needle assembly 1 is ready to transport telescoping shield to the fully extended position shown in Fig. 5 when cannula 2 is removed from the patient's skin 30.

Thus claim 1, and dependent claims 2-9, 13-16, and claim 19 and dependent claims 20, 22, 23, 25, 26 and claim 27 and dependent claims 28-32 and 34 are not anticipated by the Newby reference.

Claims Rejections – 35 USC § 103

(B) Claims 10, 11, 17, 18, 21, 24, and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Newby in view of U.S. Patent No. 4,887,998 to Martin et al. ("Martin").

This rejection is respectfully traversed in view of claims 1, 19, 22 and 27.

Of the claims rejected, claims 10, 11, 17, and 18 are dependent on claim 1, claim 21 is dependent on claim 19, claim 24 is dependent on claim 22 and claim 33 is dependent on claim 27.

To establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure (see MPEP §2143).

The invention defined by claims 1, 19, 22 and 27 are neither taught nor rendered obvious by the cited references.

Both Newby and Martin have no suggestion of a retaining member which prevents deployment of the safety shield to the fully extended shielded position upon release of the lock that maintains the safety shield in its retracted position.

As noted above, in Newby, the telescoping shield is designed to advance to the fully extended locked position automatically on release of such lock.

Similarly Martin teaches a hypodermic needle guard with a spring driven shield that is retained by a lock in a retracted position and is designed to advance to the fully extended locked position automatically on release of such a lock.

In contrast, in the present invention, as defined by claims 1, 19, 22 and 27, the telescoping shield is designed not to advance to the fully extended locked position on release of such lock, but has a retaining member that prevents such deployment.

Accordingly, it is submitted that the holder assembly as defined by claims 1, 19, 22 and 27 is **not** taught or suggested either alone or by the combination of Newby and Martin.

Therefore as claims 10, 11, 17, and 18 are dependent on claim 1, claim 21 is dependent on claim 19, claim 24 is dependent on claim 22 and claim 33 is dependent on claim 27, claims 10, 11, 17, 18, 21, 24, and 33 are patentable over the cited references.

CONCLUSION

In view of the remarks herein, applicant submits the claims are patentably distinct over the prior art and allowable in form.

The Commissioner is hereby authorized to charge payment of any additional fees associated with this communication or credit any overpayment to Deposit Account No. 02-1666.

If the Examiner has any questions or comments relating to the present application, he or she is respectfully invited to contact applicants' agent at the telephone number set forth below.

Respectfully submitted,

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